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09/936,5	09/14/2001	Naoki Tsuchiya	Q66152	8705

7590

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EXAMINER

STOCKTON, LAURA

ART UNIT

PAPER NUMBER

1626

9

DATE MAILED: 03/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.



ART UNIT	PAPER NUMBER
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DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on January 30, 2003
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-21 ☐ are pending in the application.
Of the above, claim(s) 3 ☒ is/are withdrawn from consideration.
☐ Claim(s) _____ ☐ is/are allowed.
☒ Claim(s) 1, 2 and 4-21 ☐ are rejected.
☐ Claim(s) _____ ☐ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

***Certified copies not received:**

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3, 4 and 6
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

09/936,566

DETAILED ACTION

Claims 1-21 are pending in the application.

Election/Restrictions

Applicant's election without traverse of Group IV, claims 1, 2 and 4-21 in Paper No. 8 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Subject matter not embraced by elected Group IV and Claim 3 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions. Election was made **without** traverse in Paper No. 8.

It is suggested that in order to advance prosecution, the non-elected subject matter be canceled when responding to this Office Action.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: "Benzimidazole derivatives which are inhibitors against Human Chymase".

Independent claim 1 is being interpreted as a compound claim and therefore, prior art has been applied based on this interpretation.

Claim Objections

Claims 5-9, and 15-21 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Note, claim 21 has also been objected to for depending on an improper multiple dependent claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C.

112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2 and 4-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the preamble "An inhibitor against human chymase activity containing a benzimidazole derivative expressed by the following formula (1)" should be changed to "A benzimidazole derivative expressed by the following formula (1)". See dependent claims 2, 4-9, 20 and 21 for same.

Claim 10 is indefinite because a number of variables in this independent claim are not defined (e.g., A, X¹, X², B, etc.). Therefore, dependent claims 11-18 lack antecedent basis from claim 10.

Claim 16 lacks antecedent basis from claim 10 because it states in claim 10 that J is a substituted naphthalene ring whereas in claim 16, J represents an optionally substituted phenyl {formula (2)} or an optionally substituted naphthalene ring {formula (3)}.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the

conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2 and 4-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-6, 8-11, 13 and 15 of copending Application No. 09/743,483. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims in application '483 differ only by generic description of the products. See, for example, claim 1 in application '483 and especially compound 444 in Table 18 on page 33.

One skilled in the art would thus be motivated to prepare products embraced by application '483 to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful as human chymase inhibitors. Therefore, the instant claimed products would have been suggested to one skilled in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-9 and 19-21 are rejected under 35 U.S.C. 102(a) as being anticipated by:

- a) Matsumoto et al. {WO 2000/003997} – see in an English language equivalent, EP 1,097,926 of the WO, for example, Compound No. 444 in Table 18 on page 22;

b) Screening Collection (catalog published March 28, 2000) – see CA Registry Nos. 309281-42-3, 309281-37-6 and 312505-00-3; and

c) Peakdale Fine Chemicals Product List (catalog published July 7, 2000) – see CA Registry No. 392233-94-2.

Each of the above cited prior art disclose products embraced by the instant claims.

Claims 1, 2, 4-9 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by:

a) Yoshida et al. {JP 03-014566 or CA 115:71600, 1991} – see CA Registry No. 134464-63-4;

b) Nicolai et al. {Journal of Medicinal Chemistry (1993), 36(9), pages 1175-1187} – see, for example, Tables IV, V and VI on pages 1181, 1182 and 1183, respectively, compounds 7a, 7b, 7c, etc.;

- c) Bru-Magniez et al. {U.S. Pat. 5,021,443} – see, for example, Example 63 in column 29;
- d) Bru-Magniez et al. {U.S. Pat. 5,124,336} – see, for example, Example 59 in column 41; and
- e) Bru-Magniez et al. {U.S. Pat. 5,128,359} – see, for example, Example 64 in column 41.

Each of the above cited prior art disclose products embraced by the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2 and 4-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bru-Magniez et al. {U.S. Pat. 5,021,443}, Bru-Magniez et al. {U.S. Pat. 5,124,336}, Bru-Magniez et al. {U.S. Pat. 5,128,359} and Matsumoto et al. {WO 2000/003997}, each taken alone or in combination with each other when similar utilities are asserted. Since the WO is in a non-English language, an English language equivalent, EP 1,097,926, has been provided and will be referred to hereinafter.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim benzimidazole products. Bru-Magniez et al. '443 (columns 1, 2 and 11 ; or Example 63 in column 29), Bru-Magniez et al. '336 (columns 1, 2, 11 and 12 ; or Example 59 in column 41), Bru-Magniez et al. '359 (columns 1, 2, 11 and 12 ; or Example 64 in column 41) and Matsumoto et al. (pages 2-3; or Compound No. 444 in Table 18 on page 22) each teach benzimidazole products which are either

structurally the same as (see above 102 rejections) or structurally similar to the instant claimed products.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the products of the prior art and the products instantly claimed is that of generic description.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The indiscriminate selection of “some” among “many” is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., a human chymase inhibitor).

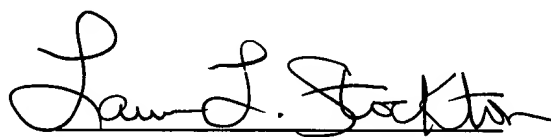
One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, myocardial infarction, migraines,

bronchial asthma, etc. Therefore, the instant claimed products would have been suggested to one skilled in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (703) 308-1875. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

A handwritten signature in cursive script, reading "Laura L. Stockton".

Laura L. Stockton, Ph.D.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

March 27, 2003